Citation:

Finley JW, Burrell JB, Reeves PG. Pinto bean consumption changes SCFA profiles in fecal fermentations, bacterial populations of the lower bowel, and lipid profiles in blood of humans. *J Nutr.* 2007 Nov;137(11):2391-8.

PubMed ID: 17951475

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine whether the consumption of 1/2 cup (130 g) of cooked dried pinto beans per day for 12 weeks would:

- Alter in vitro fecal bacterial fermentation in a manner consistent with benefits to health, primarily toward cancer and cardiovascular disease (CVD)
- Change the populations of selected bacterial species that are associated with change in in vitro fermentation when excreted fecal material is used as the inoculum for various resistant starch (RS) substrates
- Change serum lipid profiles that are consistent with positive effects on CVD.

To determine whether any health benefits occurred, or were magnified, in volunteers preconditioned to metabolic syndrome (MetSyn) (pre-MetSyn).

Inclusion Criteria:

- Pre-screening included:
  - age
  - sex
  - waist circumference
  - general health
  - antibiotic consumption
  - willingness to eat beans
- Pre-MetSyn:
  - waist circumference $\geq$ 96.5 cm for men and $\geq$ 88.9 cm for women
  - at least one of the following criteria met:
    - serum HDL-cholesterol (HDL-C) < 55 mg/dL (1.42 mmol/L
    - serum triglyceride (TG) between 150 and 199 mg/dL (1.69 - 2.25 mmol/L)
    - fasting blood glucose between 100 and 125 mg/dL (5.6 - 6.9 mmol/L)

- blood pressure (BP) between 120/85 and 140/85 mmHg
- Control volunteers - age and sex matched to pre-MetSyn volunteers
  - waist circumference < 96.5 cm for men and < 99.9 cm for women
  - serum HDL-C, fasting TG, fasting blood glucose and BP within normal range
- Medications:
  - for pre-MetSyn: allowed to take medication for MetSyn related disorders (e.g. high blood pressure but not high blood lipids)
  - for healthy volunteers - severely restricted
- Smokers allowed

Exclusion Criteria:

- Possible need for medical attention
- Volunteers who had taken antibiotics within 6 months of the beginning of the study
- Volunteers who began taking antibiotics during the study were asked to withdraw

Description of Study Protocol:

Recruitment: local recruitment by newspaper, radio, TV, and Internet advertisements

Design: Randomized 2 x 2 factorial design (Pre-MetSyn vs controls; bean consumption vs soup consumption)

Blinding used (if applicable): not applicable

Intervention (if applicable)

- Equilibration period:
  - regular diet with restrictions:
    - no beans of any type except those provided by the study
    - no dietary supplements
    - no pre- or probiotic foods or supplements
    - no prescription or over-the-counter medication to reduce intestinal gases
- Dietary intervention:
  - 1 of 4 different bean or soup entrees per day added to normal diet
    - pinto beans containing 130 g (1/2 cup) OR
    - chicken soup that was isocaloric and isonitrogenous as much as possible to bean entree

Statistical Analysis

- Power calculation (20 per group) based on power analysis of results of a previous similar clinical trial
- Change score for some variables: baseline value (equilibrium) - value obtained at end (intervention) of the study
- Test for differences in the change scores between categories (controls or pre-MetSyn) and diets (beans or soup) or their interaction: two-way ANOVA
- No interactions found, therefore, no post-hoc tests conducted

Data Collection Summary:

Timing of Measurements

- Baseline: after 4 week equilibration period
- End: after 12 week dietary intervention

Dependent Variables

- Blood lipids: total cholesterol (TC), lipoprotein fractions, total TG
- Hematology (red and white cell count, platelets, hematocrit, red cell size distribution)
- C-reactive protein
- Blood acetate
- Short chain fatty acid (SCFA) production - in vitro fermentation (fecal sample from single bowel movement)
    - substrates: bean powder, cornstarch, inulin, oat bran, or no substrate controls
- Fecal bacteria species
- Breath methane

Independent Variables

- Diet: bean soup vs chicken soup
    - dietary intake: 3-day food records

Control Variables

- Participants were asked to consume no beans of any type except those provided by the study, no dietary supplements, no pre- or probiotic foods or supplements, and no prescription or over-the-counter medication to reduce intestinal gases.

Description of Actual Data Sample:

Initial N: N = 80

- Males: N = 40:
    - control: N = 20 (10 Soup, 10 Beans)
    - Pre-MetSyn: N = 20 (10 Soup, 10 Beans)
- Females: N = 40
    - control: N = 20 (10 Soup, 10 Beans)
    - Pre-MetSyn: N = 20 (10 Soup, 10 Beans)

Attrition (final N): N = 73

- Males: N = 39
- Females: N = 34

Age: range: 18 to 55 years

- mean ($\pm$ SD) age ranges for groups: 30.7 $\pm$ 12.3 to 44.3 $\pm$ 12.1

Ethnicity: Not specified

Other relevant demographics: None specified

Anthropometrics

Anthropometric characteristics (mean ± SD) of subjects at study entry

	WOMEN				MEN			
	Control		Pre-MetSyn		Control		Pre-MetSyn	
	Soup	Beans	Soup	Beans	Soup	Beans	Soup	Beans
Weight (kg)	59.9 ± 4.4	62.9 ± 10.3	90.6 ± 13.1	89.2 ± 14.0	82.4 ± 9.8	76.3 ± 8.1	99.6 ± 10.1	102.7 ± 11.0
Fat-free weight (kg)	43.4 ± 3.0	45.8 ± 5.8	61.4 ± 9.2	61.9 ± 8.6	65.1 ± 6.2	62.3 ± 5.4	76.8 ± 8.7	79.0 ± 8.4
Fat weight (kg)	15.3 ± 3.1	16.9 ± 5.6	27.3 ± 7.0	29.9 ± 8.1	14.2 ± 3.7	119 ± 4.4	20.3 ± 2.1	21.9 ± 5.0
Waist circumference (cm)	77.7 ± 4.6	77.5 ± 6.1	103.2 ± 11.9	105.3 ± 14.5	88.3 ± 6.3	83.3 ± 5.5	106.8 ± 8.0	108.9 ±10.2
Waist:hip ratio	0.83 ± 0.05	0.83 ± 0.06	0.88 ± 0.06	0.89 ± 0.05	0.92 ± 0.04	0.91 ± 0.05	0.99 ± 0.06	0.97 ± 0.07
BMI (kg/m^2)	22.7 ± 1.8	23.3 ± 3.2	33.1 ± 3.6	34.5 ± 5.6	26.0 ± 3.0	23.9 ± 2.7	31.9 ± 3.4	31.8 ± 2.0

Location: United States

Summary of Results:

Key Findings

- When expressed as a difference between baseline and treatment, propionate production from fecal material fermented in vitro with bean flour was higher ($P < 0.02$) in volunteers consuming beans than in those consuming soup.
- During the treatment period alone, bean consumption did not affect propionic acid production with any substrate but lowered ($P < 0.02$) butyric acid production when cornstarch was the substrate.
- In all volunteers, bean consumption decreased fecal production of isovaleric ($P < 0.05$) and isobutyric ($P < 0.002$) acids from cornstarch by as much as 50%.
- Of the bacterial populations tested, only *Eubacterium limosum* was affected by bean consumption and was 50% lower than in those consuming soup
- Beans lowered serum total cholesterol ($P < 0.014$) by 8% in the controls and 4% in the pre-MetSyn group.
- Bean consumption lowered serum HDL cholesterol ($P < 0.05$) and LDL cholesterol ($P < 0.05$) without affecting serum triglycerides, VLDL cholesterol or glucose.

Dietary intake:

- As a a result of dietary intervention of 1/2 cup bean or chicken soup per day, subjects

consumed more (P< 0.001) fiber during intervention compared with equilibration.
    - Control and preMetSyn groups did not differ.
- Pre-MetSyn subjects consumed
    - more protein (P < 0.025) than controls during equilibration and during intervention
    - more lipid (P < 0.005) than controls
        - All subjects consumed less lipid (P < 0.001) during intervention compared with equilibration

Objective 1: Effects of bean consumption on in vitro fecal bacterial fermentation and production of SCFA

- Substrate used had a large effect on SCFA production.
- In those who consumed beans, compared with those who consumed chicken soup:
    - propionic acid (P < 0.02) and total fatty acids (P < 0.05) productions (mmol/kg dry feces) were higher, only when bean flour was used as the substrate.
        - no effect of Pre-MetSyn
- 2 x 2 factorial analysis:
    - bean consumption vs chicken soup:
        - no effect of bean consumption on total SCFA production, regardless of substrate
        - acetic acid concentrations not affected by bean consumption
        - butyric acid production from cornstarch was lower (P < 0.02) with bean consumption than chicken soup consumption
        - production of isovaleric acid from cornstarch (P < 0.05) and oat bran (P < 0.03) lower with bean consumption
        - isobutyric acid production from cornstarch (P < 0.002), inulin (P < 0.03), and oat bran (P < 0.02) lower with bean consumption
    - Pre-MetSyn vs controls:
        - total *SCFA* was higher in pre-MetSyn subjects than controls with cornstarch (P < 0.02) and insulin (P < 0.003) substrates
        - propionic acid production from cornstarch and oat bran was higher (P < 0.05) in Pre-MetSyn than controls.
        - butyric acid production from inulin was higher (P < 0.002) in pre-MetSyn than controls, but was not affected by bean consumption
        - isobutyric acid higher (P < 0.03) in pre-MetSyn than controls

Objective 2: Changes in bacterial populations with bean consumption

- no significant effect of bean consumption on most of the bacteria populations except for *Eubacterium limosum.*
    - *E. limosum* was lower with bean consumption (P < 0.009) between pre- and posttreatment compared with chicken soup consumption in both control and pre-MetSyn groups
- *Peptostreptococcus productus* was higher (P < 0.01) in pre-MetSyn compared with controls, but was not affected by bean consumption

Objective 3: Changes in serum lipid profiles with bean consumption

- Changes in TC (P < 0.014) and HDL-C (P < 0.05) between pre- and post-treatment were lower with bean consumption compared to soup in all subjects
    - ~ 8% reduction in controls
    - ~ 4% reduction in pre-MetSyn
- HDL-C:

- 8% reduction in controls
- 4% reduction in Pre-MetSyn

- LDL-C
  - ~ 7% reduction with bean consumption ($P < 0.05$)
  - no effect of pre-MetSyn compared with controls
- serum TG, VLDL-C, or glucose
  - no effect of bean consumption on serum levels

Author Conclusion:

Bean consumption of at least 100 grams per day can improve lipid profiles associated with cardiovascular disease; individuals with pre-MetSyn may benefit as much if not more than normal individuals. Bean consumption does not clearly confer health benefits related to colon cancer risk.

Reviewer Comments:

Small numbers of subjects based on power analysis of 20 per group, but not all subjects completed the trial. Subjects were age- and sex-matched, however it is unclear if there were statistically significant differences between the groups at baseline.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes

1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	No
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	???
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A

5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes

7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	???
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes